F ENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

POSORSKE, Laurence, H.
Brobeck, Phleger & Harrison LLP
Intellectual Property Department
1333 H Street, N.W., Suite 800
Washington, D.C. 20005
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
22 novembre 2001 (22.11.01)

Applicant's or agent's file reference
061308.0356

IMPORTANT NOTIFICATION

International application No.
PCT/US00/07989

International filing date (day/month/year)
27 mars 2000 (27.03.00)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address
POSORSKE, Laurence, H.
Baker Botts, LLP
1299 Pensylvania Ave., N.W.
Washington, D.C. 20004
United States of America

State of Nationality | State of Residence

Telephone No.
202 220 6000

Facsimile No.
202 220 5200

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address
POSORSKE, Laurence, H.
Brobeck, Phleger & Harrison LLP
Intellectual Property Department
1333 H Street, N.W., Suite 800
Washington, D.C. 20005
United States of America

State of Nationality | State of Residence

Telephone No.
202 220 6000

Facsimile No.
202 220 5200

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the International Preliminary Examining Authority
☐ the designated Offices concerned
☒ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Y. KUWAHARA

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

004480324

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 01 December 2000 (01.12.00)	
International application No. PCT/US00/07989	**Applicant's or agent's file reference** 061308.0356
International filing date (day/month/year) 27 March 2000 (27.03.00)	**Priority date** (day/month/year) 26 March 1999 (26.03.99)
Applicant ALLNUTT, Thomas, F., C. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

23 October 2000 (23.10.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Maria Kirchner

Telephone No.: (41-22) 338.83.38

09193744

14

PATENT COOPERATION TREATY

PCT

REC'D 29 OCT 2001
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 062308.0356	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/07989	International filing date *(day/month/year)* 27 MARCH 2000	Priority date *(day/month/year)* 26 MARCH 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant MARTEK BIOSCIENCES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand 23 OCTOBER 2000	Date of completion of this report 17 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Jackie Budgeon for LISA V. COOK Telephone No. (703)305-1235

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/07989

I. Basis of the report

1. With regard to the **elements** of the international application: *

[X] the international application as originally filed

[X] the description:
pages 1-25 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 26-27 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/07989

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-20	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial Applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

I. Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by Xu et al. (The Journal of Biological Chemistry, 1996)

Xu et al. disclose the ligand binding properties of BLBP (brain lipid-binding protein). Docosahexaenoic acid (DHA) is shown to be a ligand for BLBP. Wherein the binding affinity between the two is the highest yet reported for an fatty acid binding protein/ligand interaction. See abstract.

Although the references is silent with respect to kit configurations such limitations are inherent in the reference because it discloses all the reagents and/or materials recited in the kit claims.

II. Claims 1-12 and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Plotter et al. (U.S. 4,943,527) or ANDERS LIMITED (WO 98/03159) in view of Lee et al. (Investigative Ophthalmology & Visual Science, 1995).

Plotter et al. disclose methods of purifying lipid-binding proteins (peptide), including fused recombinant proteins that can bind phospholipid. The researchers found that the addition of either endogenous or exogenous lipids to the peptide mixture forms a lido-peptide complex composed of lipid and the lipid-binding proteins. Abstract, Figure 1, and Column 1.

ANDERS LIMITED also disclose the purification and utility of lipid binding proteins including fatty acids are use in therapeutic and diagnostic processes.

Plotter et al. and ANDERS LIMITED differ from the instant invention in not teaching the utility of the binding proteins in DHA detection.

However, Lee et al. teach that fatty acid binding proteins (FABP) bind docosahexaenoic acid (DHA).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect DHA as taught by (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): G01N 33/92, 33/577; C07K 16/18; C12N 5/18, and US Cl.: 435/4, 5, 6, 7, 7.1, 7.21, 69.6 ,968 ,805; 436/69, 166, 169, 170; 530/387.1, 387.3, 387.9, 388.1, 388.15, 388.85, 388.26, 350, 432, 412

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
Lee et al. with the purified protein ligands found in the methods of Plotter et al. or ANDERS LIMITED because such techniques were widely known.

Absent results to the contrary or unexpected results the modification is viewed as an obvious modification that does not render the claims distinct from patent no. 5,872,014.

III. Claims 13-18 lack an inventive step under PCT Article 33(3) as being obvious over Plotter et al. (U.S. 4,943,527) or ANDERS LIMITED (WO 98/03159) in view of Lee et al. (Investigative Ophthalmology & Visual Science, 1995) and in further view of Zuk et al. (U.S. 4,281,061).

The teachings of Plotter et al. or ANDERS LIMITED in view of Lee et al. are set forth above. However, these references fail to teach the assay as a kit.

Zuk et al. teach that "as a matter of convenience the reagents [of an immunoassay} can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66). It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the DHA detection assay as taught by Plotter et al. or ANDERS LIMITED in view of Lee et al. and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre measured amounts which eliminates the variability that can occur when performing the assay.

---------- NEW CITATIONS ----------

Database BIOSIS on STN, AN 1995:200717. LEE et al. 'Cultured monkey pigment epithelial (PE) cells contain a fatty acid binding protein (FABP) that binds docosahexaenoic acid (DHa.' Investigative Ophthalmology & Visual Science. 1995, Vol. 36, No. 4, page S138.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07989

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :G01N 33/92, 33/577; C07K 16/18; C12N 5/18.

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435 4.5,6,7,7.1,7.21,69.6,968,805; 436 69,166,169,170; 530 387.1,387.3,387.9,388.1,388.15,388.85,388.26,350,432,412

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

East / West patent database

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN-biosis and caplus

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N
X	XU, L.Z. et al. Ligand Specificity of Brain Lipid-binding Protein. Journal of Biological Chemistry. 1996, Vol. 271, No. 40, pages 24711-24719, see entire document.	1-20
Y	US 5,777,141 A (BRUNNER et al) 07 July 1998, see entire document.	1-13
Y	US 5,550,156 A (KYLE) 27 August 1996, see entire document.	1-13
Y	US 5,397,591 A (KYLE et al) 14 March 1995, especially col 6.	1-13
Y	WO 98/03159 A2 (ANDARIS LIMITED) 29 January 1998, see entire document	1-13

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents.

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 MAY 2000

Date of mailing of the international search report

21 JUN 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

LISA V. COOK

JOYCE BRIDGERS
PARALEGAL SPECIALIST
CHEMICAL MATRIX

Telephone No. (703)305-1235

Form PCT/ISA/210 (second sheet) (July 1998)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07989

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim
Y	US 4,943,527 A (PROTTER et al) 24 July 1990, see entire document.	1-13
Y	US 4,281,061 A (ZUK et al) 28 July 1981, see entire document.	14-20

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: LAURENCE H. POSORSKE
BROBECK, PHLEGER & HARRISON LLP
1333 H STREET, N.W. SUITE 800
WASHINGTON, D.C. 20005

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	24 OCT 2001
Applicant's or agent's file reference: 062308.0356	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US00/07989	27 MARCH 2000	26 MARCH 1999

Applicant
MARTEK BIOSCIENCES CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	LISA V. COOK Faye Bridges for
Facsimile No. (703) 305-3230	Telephone No. (703)305-1235

Form PCT/IPEA/416 (July 1992) ★

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 062308.0356	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/07989	International filing date *(day/month/year)* 27 MARCH 2000	Priority date *(day/month/year)* 26 MARCH 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant MARTEK BIOSCIENCES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 OCTOBER 2000	17 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LISA V. COOK Telephone No. (703)305-1235

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/07989

I. Basis of the report

1. With regard to the **elements** of the international application: *

[X] the international application as originally filed

[X] the description:
pages 1-25 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 26-27 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

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4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/07989

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-20	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial Applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

I. Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by Xu et al. (The Journal of Biological Chemistry, 1996)

Xu et al. disclose the ligand binding properties of BLBP (brain lipid-binding protein). Docosahexaenoic acid (DHA) is shown to be a ligand for BLBP. Wherein the binding affinity between the two is the highest yet reported for an fatty acid binding protein/ligand interaction. See abstract.

Although the references is silent with respect to kit configurations such limitations are inherent in the reference because it discloses all the reagents and/or materials recited in the kit claims.

II. Claims 1-12 and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Plotter et al. (U.S. 4,943,527) or ANDERS LIMITED (WO 98/03159) in view of Lee et al. (Investigative Ophthalmology & Visual Science, 1995).

Plotter et al. disclose methods of purifying lipid-binding proteins (peptide), including fused recombinant proteins that can bind phospholipid. The researchers found that the addition of either endogenous or exogenous lipids to the peptide mixture forms a lido-peptide complex composed of lipid and the lipid-binding proteins. Abstract, Figure 1, and Column 1.

ANDERS LIMITED also disclose the purification and utility of lipid binding proteins including fatty acids are use in therapeutic and diagnostic processes.

Plotter et al. and ANDERS LIMITED differ from the instant invention in not teaching the utility of the binding proteins in DHA detection.

However, Lee et al. teach that fatty acid binding proteins (FABP) bind docosahexaenoic acid (DHA).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect DHA as taught by (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): G01N 33/92, 33/577; C07K 16/18; C12N 5/18, and US Cl.: 435/4, 5, 6, 7, 7.1, 7.21, 69.6 ,968 ,805; 436/69, 166, 169, 170; 530/387.1, 387.3, 387.9, 388.1, 388.15, 388.85, 388.26, 350, 432, 412

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
Lee et al. with the purified protein ligands found in the methods of Plotter et al. or ANDERS LIMITED because such techniques were widely known.

Absent results to the contrary or unexpected results the modification is viewed as an obvious modification that does not render the claims distinct from patent no. 5,872,014.

III. Claims 13-18 lack an inventive step under PCT Article 33(3) as being obvious over Plotter et al. (U.S. 4,943,527) or ANDERS LIMITED (WO 98/03159) in view of Lee et al. (Investigative Ophthalmology & Visual Science, 1995) and in further view of Zuk et al. (U.S. 4,281,061).

The teachings of Plotter et al. or ANDERS LIMITED in view of Lee et al. are set forth above. However, these references fail to teach the assay as a kit.

Zuk et al. teach that "as a matter of convenience the reagents [of an immunoassay} can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66). It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the DHA detection assay as taught by Plotter et al. or ANDERS LIMITED in view of Lee et al. and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre measured amounts which eliminates the variability that can occur when performing the assay.

---------- NEW CITATIONS ----------

Database BIOSIS on STN, AN 1995:200717. LEE et al. 'Cultured monkey pigment epithelial (PE) cells contain a fatty acid binding protein (FABP) that binds docosahexaenoic acid (DHa.' Investigative Ophthalmology & Visual Science. 1995, Vol. 36, No. 4, page S138.